K091381

BIOMET SPINE

510(k) Summary

AUG 07 2009

Preparation Date:	August 6, 2009
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly Phone: 973-299-9300 Fax: 973-257-0232
Trade name:	Ibex™ Spinal System
Common Name:	Non-cervical spinal spacer
Classification Name:	Intervertebral fusion device, 21 CFR §888.3080 Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060
Device Panel /Product Code:	Orthopedic MAX & MQP

Device Description:

The Ibex™ Spinal Spacer is a curved device constructed of either Titanium alloy or medical grade Polyetheretherketone (PEEK) with tantalum radiographic markers for spinal applications.

Indications for Use:

The Ibex™ Spinal System is indicated for vertebral body replacement and intervertebral fusion. When used for vertebral body replacement, the Ibex™ Spinal System is indicated for use in the thoracolumbar spine (i.e., T1- L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Ibex™ Spinal System is also indicated for treating fractures of the thoracic and lumbar spine. The Ibex™ Spinal System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time.

As an intervertebral body fusion device, the Ibex™ Spinal System is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The Ibex™ Spinal System is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The Ibex™ Spinal System may also be implanted using the Accuvision System to provide the surgeon with a minimally invasive approach for posterior or posterolateral spinal surgery.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Ibex™ Spinal Spacer is the same as, or similar to, the predicate devices.

Substantial Equivalence:

The Ibex™ Spinal System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. An example of a predicate intervertebral body fusion device distributed for the similar indications includes the Expandable PEEK Implant (K040928 and K082406) and the Ibex™ Spinal System (K042268 & K050861) has similar design features. Based upon the mechanical testing, Ibex™ Spinal System is substantially equivalent for its intended use to other spacers currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 07 2009

Biomet Spine
% Ms. Vivian Kelly
Regulatory Affairs Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K091381
Trade/Device Name: IBEX™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: May 8, 2009
Received: May 11, 2009

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091381

Device Name: Ibex™ Spinal System

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(TEXT FOR MXM)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091381

page 1 of 1